UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

ISIS PHARMACEUTICALS, INC.,

Plaintiff,

vs.

SANTARIS PHARMA A/S CORP., et al.,

Defendant.

CASE NO. 11cv2214-GPC (KSC)

ORDER DETERMINING DISPUTE RE: DR. DEAN

[Doc. Nos. 149, 162]

Pending before the Court is the parties' Supplemental Joint Motion for Resolution of Dispute concerning plaintiff's proposed testifying expert, Dr. Nicholas M. Dean. [Doc. No. 149 (unsealed); Doc. No. 162 (sealed)] Defendants object to the disclosure to Dr. Dean of documents and information designated by defendants as "Confidential" and "Confidential - Outside Counsel Only" under the Amended Protective Order [Doc. No. 144] entered by the Court in this matter. After considering the arguments presented in the Joint Motion, and balancing the risk of inadvertent disclosure to defendants against the prejudice to plaintiff's ability to prosecute its case, the Court finds that plaintiff shall be permitted to disclose to Dr. Dean documents and information designated by defendants as highly confidential and proprietary under the Amended Protective Order, subject to the protections contained therein.

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I. BACKGROUND

Plaintiff Isis Pharmaceuticals ("Isis" or "plaintiff") alleges defendants Santaris Pharma A/S Corp. and Santaris Pharma A/S (collectively, "Santaris" or "defendants") have infringed upon two of plaintiff's patents. The two patents at issue in this litigation involve a form of biotechnology called antisense molecules. Antisense molecules are generally used to interrupt the overproduction or abnormal production of certain proteins that can cause disease.

On October 25, 2012, after reviewing the parties' joint request for a Protective Order [Doc. No. 58], the Court entered a Protective Order [Doc. No. 59] in this matter. Due to the highly proprietary nature of information being exchanged in this case, and the economically competitive nature of the litigants, the Protective Order created two designations for sensitive information: "Confidential" and "Confidential - Outside Counsel Only" (hereinafter Counsel Only). [Doc. No. 59, pp. 2-8] Paragraph 4 holds that designation as Confidential is appropriate only if the designating party has a good faith belief that the "unrestricted disclosure of the information could be potentially prejudicial to the business or operations of the party," and that designation as Counsel Only is appropriate only if the designating party has a good faith belief that the information is "most sensitive" to the party, "including but not limited to trade secret or other confidential research (for example, nonpublic target names, target sequences, and target identifiers), development, financial or other commercial information." [Doc. No. 59, pp. 2-3] Paragraphs 8 and 9 of the Protective Order limit the exchange of Confidential and Counsel Only information to certain individuals, including "independent experts under the conditions set forth in [Paragraph 8]." [Doc. No. 59, p. 5] The Protective Order contains an additional provision granting one party fourteen (14) days to object to another party's designation of an independent expert prior to the disclosure of the Counsel Only information. *Id.* Finally, the Protective Order provides that "[t]he approval of independent experts shall not be unseasonably withheld." *Id.*

Plaintiff retained Dr. Nicholas Dean to provide expert opinions and information

regarding the antisense drug discovery process as it relates generally to the two patents at issue in this trial. Defendants timely objected to plaintiff's designation of Dr. Dean as an independent expert, contending that there was a significant risk of harm associated with disclosure of their confidential information to Dr. Dean given his current consultancy in the area of antisense technology and his past professional relationship with plaintiff. Notwithstanding defendants' objections to Dr. Dean, plaintiff sought court approval designating Dr. Dean as an "independent expert" under the terms of the Protective Order. Accordingly, on March 8, 2013, the parties filed a Joint Motion seeking determination of their dispute [Doc. No. 113] regarding Dr. Dean's access to defendants' confidential information produced in this action.

On May 6, 2013, a Discovery Hearing was held [Doc. No. 134] before Magistrate Judge Crawford to hear argument regarding the parties' original Joint Motion for Resolution of Dispute [Doc. No. 113] concerning Dr. Dean. On May 17, 2013, after considering the oral arguments and the arguments contained in the Joint Motion, the Court issued an Order directing plaintiff to disclose the names of all of the companies for which Dr. Dean currently consults, and has consulted within the last four years, as well as the time period(s) for each and a brief description of the nature and subject matter of each consultancy. [Doc. No. 140, citing S.D. Cal. Form Protective Order (Appended to Local Patent Rules), ¶ 12, pp. 6-7] The Court also ordered the parties to jointly submit for the Court's signature "an Amended Protective Order, already signed by the parties, revising the Protective Order already entered in this case [Doc. No. 59] by including Paragraph 12 from the Southern District's Model Protective Order for patent cases, which is appended to the Southern District's Local Patent Rules and can be accessed via the Court's website, www.casd.uscourts.gov." [Doc. No. 140, p. 6]

On June 3, 2013, an Amended Protective Order was entered [Doc. No. 144], based upon the joint submission of the parties. Included in Paragraph 8 of the Amended Protective Order, as ordered, was the language from Paragraph 12 of the

Southern District Model Protective Order for patent cases. However, tacked onto the Court-ordered clause was an additional sentence purporting to define the term "Independent Expert." [Doc. No. 144, p. 6] This additional language exceeded the scope of the Court's May 17, 2013 Order [Doc. No. 140] instructing the parties to add Paragraph 12 from the Southern District's Model Protective Order for patent cases. The Court's May 17, 2013 Order did not authorize any additional amendments beyond the inclusion of Paragraph 12 from the model protective order. Furthermore, when the Amended Protective Order was submitted to the Court, the parties failed to disclose that changes had been made beyond the one amendment specifically ordered. Accordingly, the last sentence in Paragraph 8 of the Amended Protective Order[1], shall be **stricken** from the Amended Protective Order.[2]

II. LEGAL STANDARD

The scope of discovery under Rule 26(b) is broad: "[p]arties may obtain discovery regarding any matter, not privileged, which is relevant to the claim or defense of any party involved in the pending action. FED.R.CIV.P.26(b)(1). However, upon a showing of "good cause," Rule 26(c) gives courts substantial latitude and discretion in directing or limiting discovery. FED.R.CIV.P.26(c) ("The court may, for good cause, issue an order to protect a party from annoyance, embarrassment, oppression, or undue burden or expense."). Specifically, the court is empowered to control whether or how certain confidential information is revealed during the course of discovery. *Id.* at 26(c)(1)(G).

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[1] The sentence to be stricken is the last of Paragraph 8 and can be found on page 6 of the Amended Protective Order. It states, "The term 'Independent Expert' means a person with specialized knowledge or experience in a matter pertinent to the case who has been retained by Counsel to serve as an expert witness or as a litigation consultant in this case, and who is not a current employee of a party or of a competitor of a party and who, at the time of retention, is not anticipated to become an employee of, or a non-litigation consultant of a party or competitor of a party." [Doc. No. 144, p. 6]

[2] Paragraph 28 of the Amended Protective Order entered in this case gives the Court the right to modify the Protective Order "in the interests of justice or for public policy reasons." [Doc. No. 144, p. 13]

When dealing with confidential information, a court may compel the production of such information while simultaneously restricting those who may access it. *See Brown Bag Software v. Symantec Corp.*, 960 F.2d 1465, 1470 (9th Cir. 1992) (finding "protection from misuse of trade secrets by competitors" as good cause for restricting access). "When a party is concerned about the competitive misuse of confidential information and a protective order appears to be insufficient protection, the court must balance the risk of disclosure to competitors against the risk of damaging the claims or defenses of the party seeking access." *Santella v. Grizzly Industries, Inc.*, 2012 WL 5399970 at *4 (D. Or. Nov. 5, 2012) (citing *Brown Bag* and applying it to the expert witness context). Before granting or denying access to confidential information to in-house counsel, an expert witness, or another litigation participant, a court "must examine factually all of the risks and safeguards surrounding inadvertent disclosure." *Brown Bag*, 960 F.2d at 1470.

Where the parties have agreed to, and the court has entered, a protective order, "the party opposing disclosure [of confidential information] has the burden of establishing that there is good cause to continue the protection of the discovery material." *In re Roman Catholic Archbishop of Portland*, 661 F.3d 417, 424 (9th Cir. 2011) *cert. denied*, 132 S.Ct. 1867 (U.S. 2012). In this case, a protective order has been entered [Doc. No. 59 (Protective Order), Doc. No. 144 (Amended Protective Order)]; however, defendants oppose disclosure of their confidential information to plaintiff's expert, Dr. Dean. Accordingly, defendants bear the burden of showing why the risk of disclosure of its confidential information outweighs the risk of harm to plaintiff's ability to prosecute its case. For the reasons outlined below, the Court finds that defendants have failed to meet this burden.

III. DISCUSSION

Defendants object to the disclosure of their Confidential and Counsel Only information to plaintiff's proposed expert, Dr. Dean, because he has a longstanding

relationship with plaintiff and he actively consults in defendants' same industry. Regarding his relationship with plaintiff, defendants cite that Dr. Dean spent nearly 15 years working at Isis (April 1991 to January 2006) where he co-invented over 40 patents now assigned to Isis, and that he was the Founder, Board Member, and Chief Scientific Officer of Excaliard (January 2006 to February 2012), a company which did substantial business with Isis until Excaliard was purchased by Pfizer in February 2012. With respect to Dr. Dean's consultancy work, since Excaliard's sale, Dr. Dean has served as a consultant to various drug discovery companies and foundations through his sole proprietorship consultancy.

Plaintiff argues that Dr. Dean's relationship with Isis ended over 7 years ago, that Isis's relationship with Excaliard did not contain the deep technical and financial ties alleged by defendants, that his current consultancy work is in "therapeutic areas" separate and distinct from those defendants are currently pursuing, that Dr. Dean has agreed to be bound by the patent prosecution bar contained in the Amended Protective Order entered in this case, and that despite contacting numerous other potential experts, plaintiff has been unable to locate a suitable alternative expert with equivalent practical experience in the areas of drug discovery and development.

A. Risk of Inadvertent Disclosure

Defendants do not contend that Dr. Dean will *intentionally* violate the terms of the Amended Protective Order by voluntarily disclosing or otherwise utilizing defendants' confidential information. Rather, defendants' argue that, due to Dr. Dean's past relationship with plaintiff as well as his present work as a consultant with competitors in the field, their confidential information will be inadvertently disclosed during the course of future engagements. Thus, the issue posed is, given Dr. Dean's past affiliation and present engagements, is he capable of "lock[ing]-up [the confidential information] in his mind, safe from inadvertent disclosure" in present and future consultancies. *Brown Bag*, 960 F.2d at 1471. In evaluating

whether there is a risk of inadvertent disclosure, the Ninth Circuit has found that a "crucial factor" is whether the person seeking access is "involved in 'competitive decision-making'; that is, advising on decisions . . . 'made in light of similar or corresponding information about a competitor.'" *Brown Bag*, 960 F.2d at 1470 (quoting *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 n. 3 (Fed. Cir. 1984)). The parties disagree about whether Dr. Dean is a "competitive decision-maker" in his role as consultant and further disagree about whether these entities qualify as "competitors" in the field.

1. Competitors in the Field

Plaintiff dismisses the notion that any of Dr. Dean's 7 disclosed consultancies are with entities which qualify as defendants' direct competitors. Specifically, plaintiff contends 2 of the 7 do not utilize antisense technologies at all, that another 2 "utilize an altogether different approach to gene inhibition called RNA interference," and that another focuses on technology that complements, but does not compete with, antisense therapies. [Doc. No. 162, pp. 12-13] With respect to the entity for which Dr. Dean consults which is referred to as "Company" in prior Motions [Doc. No. 113] and at the prior Discovery Hearing [Doc. No. 134], while conceding that "Company" does utilize antisense technology, plaintiff argues "Company" is "developing a wound care treatment that employs antisense molecules directed to . . . a gene not among the dozens of gene targets disclosed to [plaintiff] as part of [defendants'] internal or partnered drug discovery programs." [Doc. No. 162, pp. 13]

Defendants argue that they design and develop "antisense drugs for pharmaceutical clients interested in a wide variety of targets in a wide range of therapeutic areas" and claim that "all but one of the entities that Dr. Dean currently works with is engaged in the field of antisense technology." [Doc. No. 162, pp. 22-23] Defendants consider at least some of the specific entities identified by Dr. Dean as "direct competitors." *Id.* at 24. Dr. Dean's most significant consulting

engagement with "Company" potentially presents a direct conflict, as the documents produced in this litigation reveal that both defendant and "Company" were investigating the exact same gene target. *Id.* However, this specific instance aside, defendants contend that its "competitors are not limited to those companies who are currently working on the same target or conducting research within the same therapeutic area..." because defendants' proprietary antisense technology may be applied in virtually every therapeutic area and, "even if [defendants] and one of Dr. Dean's clients are currently working on developing antisense drugs to treat different conditions, [defendants] could have competed for the contract for the same work." *Id.* at 23.

To further support their argument, defendants cite to plaintiff's evolving definition of "competition." Previously, in plaintiff's March 23, 2012 Opposition to defendants' original Motion for Summary Judgment [Doc. No. 22], plaintiff stated that defendants directly compete with plaintiff "by selling antisense drug discovery services and products . . . to pharmaceutical company customers in the United States." [Doc. No. 22, p. 5] However, in the instant Supplemental Joint Motion, plaintiff narrows the term "competition" by defining it as entities working on or towards the same therapeutic targets or areas. This shift, defendants argue, is "artificial and inaccurate." [Doc. No. 162, p. 23]

Based on the arguments presented regarding defendants' business, the antisense field in general, and the specific entities for whom Dr. Dean consults, the Court finds that plaintiff, defendants, and the named entities are all competing, either directly or indirectly. Given that defendants claim their proprietary antisense technology may be applied in virtually every therapeutic area, and that "Company" and defendants were both investigating the exact same target, all the entities involved are operating within the same competitive economic market. The Court is not persuaded by plaintiff's arguments that Dr. Dean's consultancies involve different therapeutic areas, given the overlap in gene targeting by "Company" and

defendants. This mutual targeting reveals that defendants are competitors, even if the mutually targeted gene is not the subject of this litigation.

2. Competitive Decision-Maker

"[A] competitive relationship alone . . . is not sufficient to find that [a proposed expert] will inadvertently disclose [the producing party's] confidential information." *Santella*, 2012 WL 5399970 at *6 (citing and applying *Brown Bag*). As stated above, a "crucial factor" in weighing the risk of inadvertent disclosure is determining whether a party qualifies as a competitive decision-maker, specifically, one "in a position to effectuate or direct decisions made using knowledge that is tainted by . . . confidential information [made in light of similar or corresponding information about a competitor]." *Santella*, 2012 WL 5399970 at *6 (citing *Brown Bag*, 960 F.2d at 1470). However, the risk of inadvertent disclosure does not arise solely from an information recipient's level of influence within an entity, but rather, from being "in a position where the subtle percolation of the confidential information can tangibly and unavoidably alter the recipient's actions." *Santella*, 2012 WL 5399970 at *6 (quoting *FTC v. Exxon Corp.*, 636 F.2d 1336, 1350 (D.C. Cir. 1980) ("[I]t is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the recipient.")). As explained by the *Santella* Court, "despite the decision-maker's best conscious effort his or her future . . . decisions may be made in partial reliance on that information." *Santella*, 2012 WL 5399970 at *6.

In other words, the recipient's role and position as a decision maker in a company, as well as the type of information at issue is determinative. Given the nature of Dr. Dean's past professional relationships and current engagements, as well as the type of confidential information at issue in this litigation, the appropriate inquiry is whether Dr. Dean can "lock-up trade secrets in his mind" when engaged as a consultant. Plaintiff argues yes, while defendants contend Dr. Dean will be unable to compartmentalize and selectively suppress confidential competitive

information once learned.

Plaintiff states Dr. Dean currently "consults as either a business development consultant or as a scientific advisor to five biotechnology companies . . . [and acts as advisor to] a private philanthropic foundation." [Doc. No. 162, p. 11] The seventh consultancy listed ended over four years ago. [Doc. No. 162, p. 11, fn. 6] Plaintiff contends that because Dr. Dean is "not an officer of any of these entities" and his "advisory role" does not put him in a position to effectuate or direct decisions, such "an arm's length relationship" fails to place him in a position likely to result in the inadvertent disclosure of defendants' confidential information. [Doc. No. 162, pp. 11-12] Defendants counter that the "very nature of Dr. Dean's consulting is to advise competitive entities - like ["Company"] - with respect to identification of targets . . . and developing drugs for those targets." [Doc. No. 162, p. 27]

In the parties' prior Joint Motion disputing Dr. Dean's access to confidential information (submitted and argued prior to plaintiff revealing Dr. Dean's consultancies), Dr. Dean described his consulting work as "provid[ing] advice" regarding which targets his client "should prioritize" among those identified to him by his client. [Doc. No. 113, Exh. 10, ¶ 16, Dean Declaration] Dr. Dean represents that "[he] do[es] not assist the client in identifying targets" and "[he] do[es] not make the ultimate decisions regarding target prioritization." *Id.* "There are tens of thousands of genes in the human genome." [Doc. No. 113, p. 3]

According to defendants, the identities of their confidential and specific targets are among their most closely guarded scientific trade secrets. As a consequence, defendants argue, "the mere disclosure of the *identity* of the targets alone–even without any other technical details–conveys information about [their] therapeutic strategy, and inherent information that the disease and gene are promising subjects for antisense therapeutics. Such information could significantly harm [defendants] and provide a vast and unfair benefit to its competitors." *Id.*

Defendants contend that the disclosure of this information to a competitor, at the very least, allows the competitor to avoid the cost of determining this information for itself. [Doc. No. 113, p. 31]

Given Dr. Dean's status as an active consultant in the field, the narrow scope of his consulting work, and the nature of the information at issue (the identities of gene targets, when there are "tens of thousands of genes in the human genome" from which to choose), the Court finds there to be some potential risk of inadvertent disclosure of defendants' confidential information. While Dr. Dean is not an officer or final decision maker for any of the entities, and thus does not qualify as a traditional "competitive decision maker," the essence of his consulting practice is to impact, shape, and inform decisions regarding the prioritizing of gene targets, namely which genes to pursue, and, equally important, which to avoid. Given Dr. Dean's agreement to be bound by the Amended Protective Order entered in this case, and the patent prosecution bar included therein, and his assurances that he would discontinue a consultancy if it triggered a conflict with something derived from defendants' confidential information in this case, there is a relatively minor risk that "despite the [Dr. Dean's] best conscious effort," his "future decisions may be made in partial reliance on that information." *Santella*, 2012 5299970 at *6. This Court finds that the modest risk of inadvertent disclosure of defendants' confidential information within this admittedly small field does not justify defendants' demand that Dr. Dean be precluded from serving as an expert witness in this case.

B. Prejudice to Plaintiff's Ability to Prosecute its Case if Dr. Dean is Precluded from Receiving Confidential Information

Plaintiff argues that Dr. Dean's experience in the antisense industry and his familiarity with drug discovery and development make him uniquely qualified, and thus necessary, to provide expert testimony in prosecuting this litigation. [Doc. No. 162, p. 16] Given that only two products have been approved by the FDA during the more than 20 year history of the antisense industry, plaintiff contends the pool of

qualified experts is small and that Dr. Dean's 30 years of experience in drug discovery and development render him an industry expert. *Id.* Further, plaintiff argues that the impending deadline for the filing of defendants' renewed Motion for Summary Judgment ("MSJ") on the Safe Harbor issue, and significant costs already expended in retaining and preparing Dr. Dean to assist in opposing defedants' original MSJ on the same issue, make it unreasonably burdensome to find a suitable replacement. *Id.* at 17.

Defendants assert there is no substantial prejudice to plaintiff because other suitable antisense experts exist, defendants have already permitted two of plaintiff's other experts to view their confidential information, and plaintiff was aware of defendants' objections to Dr. Dean over 6 months ago, and thus, were on notice of the need to potentially find a replacement. [Doc. No. 162, pp. 33-34] Furthermore, defendants claim that despite being on notice of the conflicts raised by this litigation, Dr. Dean accepted two additional consulting agreements in 2013 posing the same types of competitive risks to defendants. *Id.* at 34. Lastly, defendants contend that there is no prejudice to plaintiff because defendants are not impeding plaintiff from utilizing Dr. Dean as an expert altogether, but rather, are objecting only to the disclosure of their confidential material to him. *Id.*

In assessing the prejudice to the party seeking disclosure, the Court must consider "the nature of the claims and [the] party's opportunity to develop its case through alternative discovery procedures." *Brown Bag*, 960 F.2d at 1470. In this case, plaintiff accuses defendants of infringing upon two of plaintiff's patents covering antisense technology. Further, the immediate issue presented in defendants' renewed MSJ on the Safe Harbor issue relates to whether defendants may claim an absolute exemption from plaintiff's infringement claims. In framing the Safe Harbor issue, District Judge Moskowitz found that "[t]he Safe Harbor does not apply, however, where a biological compound is used to perform 'basic scientific research' or as a 'research tool.'" [Doc. No. 53, p. 6] Given these issues,

the Court finds that it is essential for plaintiff to have an antisense expert qualified to testify regarding the process of drug discovery and development.

"A witness who is qualified as an expert by knowledge, skill, experience, training, or education" is permitted to provide opinion testimony if the opinion is reliable, relevant to the issues in the case, and will help the fact finder reach a decision. FED.R.EVID. 702. With only two products approved by the FDA during the antisense industry's more than 20 year history, the pool of experts qualified to testify to the process of drug discovery and development is a small one. Defendants' own choice of expert further bolsters this conclusion. Defendants' expert, Dr. Robert Brown, is Chief Science Officer and Management Team member of a company that defendants' own documents identify as a competitor. [Doc. No. 162, p. 15] Plaintiff's selection of a senior management-level executive of a competitor as an expert witness and voluntary disclosure of its own confidential information to him underscores the limited number of experts in this small field who are qualified to serve as expert witnesses.[3] Were this Court to preclude Dr. Dean from serving as an expert in this case, the potential prejudice to plaintiff would be high. Based on the small size and highly specialized nature of the antisense industry, especially in light of defendants' choice of a direct competitor as its own expert, denying Dr. Dean access to defendants' confidential information will unreasonably limit and impair plaintiff's ability to prosecute its case at trial and defend itself against defendants' anticipated renewed MSJ on the Safe Harbor issue.

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[3] While defendants claim a search on Westlaw for antisense experts yields over 500 results, plaintiff argues that a high proportion of those results are duplicates (some listed 10 or more times), that many on the list are included by virtue of their publication of one or a few discrete antisense articles, and that many lack the practical expertise necessary to evaluate the Safe Harbor issue specifically and the infringement issues generally presented in this action. [Doc. No. 162, p. 17]

IV. CONCLUSION

Balancing the risks, the Court finds that the risk of unfair prejudice to plaintiff in its ability to defend against defendants' renewed MSJ on the Safe Harbor issue outweighs the potential risk of inadvertent disclosure of defendants' confidential information. Accordingly, Dr. Dean may be given access to defendants' documents marked as "Confidential" and "Confidential - Counsel Eyes Only," subject to the protections of the Amended Protective Order entered in this case.

IT IS SO ORDERED.

Date: July 5, 2013

KAREN S. CRAWFORD
United States Magistrate Judge